

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:
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PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Applicant's or agent's file reference 378/04598		Date of mailing (day/month/year) 12 JAN 2007 FOR FURTHER ACTION See paragraph 2 below
International application No. PCT/IL05/00535	International filing date (day/month/year) 25 May 2005 (25.05.2005)	Priority date (day/month/year) 27 May 2004 (27.05.2004)
International Patent Classification (IPC) or both national classification and IPC IPC: A61M 29/00(2006.01) USPC: 623/1.11,1,12,1,2		
Applicant F. D. CARDIO LTD		

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201	Date of completion of this opinion 18 December 2006 (18.12.2006)	Authorized officer: Kevin T. Truong Telephone No. 571-272-3700
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Form PCT/ISA/237 (cover sheet) (April 2005)

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/IL05/00535

Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of:

- ☒ the international application in the language in which it was filed
- ☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

- ☐ a sequence listing
- ☐ table(s) related to the sequence listing

b. format of material

- ☐ on paper
- ☐ in electronic form

c. time of filing/furnishing

- ☐ contained in the international application as filed.
- ☐ filed together with the international application in electronic form.
- ☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

WRITTEN OPINION OF THE
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International application No.
PCT/IL05/00535

Box No. V Reasoned statement under Rule 43 bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims <u>9-13, 20</u>	YES
	Claims <u>1-8, 14-19, 21-26</u>	NO
Inventive step (IS)	Claims <u>NONE</u>	YES
	Claims <u>1-26</u>	NO
Industrial applicability (IA)	Claims <u>1-26</u>	YES
	Claims <u>NONE</u>	NO

2. Citations and explanations:

Claims 1-8, 14-19, and 21-26 are lack novelty under PCT Article 33(2) as being anticipated by Shmulewitz (U.S. 5,989,263). As to claims 1-8 and 14-19, note in figures 1-3, an inner tube (30) configured to slidably within an outer tube (11); a hydraulic mechanism (35) is inherently capable of adapted to apply pushing force to the inner tube (30), such that the inner tube (30) can extend at least 200 or 500 mm; a sliding fluid seal (33 also, includes proximal enlarge portion of inner tube 30), wherein said inner tube (30) has a varying diameter and balloon (20) mounted on the distal end of said inner tube (30) and furthermore, stent mounted on the balloon (20) (see col. 3, lines 40-47 and col. 5, lines 48-63).

As to claims 22-26, wherein Shmulewitz device is clearly capable of performing the method steps as claimed.

Claims 9-13 and 20 are lack inventive step under PCT Article 33(3) as being obvious over Shmulewitz (U.S. 5,989,263) in view of Fiedler (U.S. 5,817,101).

Shmulewitz discloses the claimed invention (as shown above) except for a fluid inflation channel inside the inner tube and wherein the inflation channel being stored in a protective sheath.

However, Fiedler teaches in figures 1-3, that it is know in the surgical art to have a fluid inflation channel (26) inside the inner tube and being stored in a protective sheath (36).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the Shmulewitz device with a fluid inflation channel inside the inner tube (30) and a protective sheath covering the inflation channel as taught by Fiedler in order to navigate the vascular system for deploying and expanding an expandable stent device.

Claims 1-26 meet the criteria set out in PCT Article 33(4), and thus the invention industrial applicability because the subject matter claimed can be made or used in industry.